It's *Still* Not Too Late to Get Your Flu Vaccine

Meant to get vaccinated in the fall to ward off the flu, but somehow didn't get around to it? Think it's too late to get vaccinated now?

Not so. According to the Food and Drug Administration (FDA), vaccinations can be protective as long as flu viruses are circulating. And while seasonal flu outbreaks can happen as early as October, flu activity usually peaks in January or February, and can last well into May.

FDA plays a key role in ensuring that safe and effective influenza vaccines are available every flu season. In fact, the task of producing a new vaccine for the next flu season starts well before the current flu season ends. For FDA, it's a year-round initiative.

Why a new vaccine?

According to Marion Gruber, Ph.D., director of FDA's Office of Vaccine Research and Review, there are several reasons that new vaccines must be manufactured each year.

"Influenza viruses can change from year to year, due to different subtypes and strains that circulate each year," says Gruber. A vaccine is needed that includes virus strains that most closely match those in circulation, and the protection provided by the previous year's vaccine will diminish over time.

Identifying Likely Virus Strains

Each February, before that year's flu season ends, FDA, the World Health Organization (*www.who.int/influenza/en/*), the Centers for Disease Control and Prevention (CDC) and other public health experts collaborate on collecting and reviewing data from around the world to identify the flu viruses likely to cause the most illnesses in the next flu season. Based on that information and the recommendations of an FDA advisory committee, the agency selects the virus strains for FDA-licensed manufacturers to include in their vaccines for use in the United States.

"The closer the match between the circulating strains causing disease and the virus strains in the vaccine, the better the protection against influenza," Gruber says.

In addition, FDA inspects the manufacturing facilities on a regular basis, and prepares and provides reagents (necessary test components

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to standardize vaccines) that vaccine manufacturers need to make their vaccine and to verify its identity and strength. FDA also evaluates each manufacturer's vaccine each year for approval purposes, conducts lot release (that is, performs certain tests and reviews the results of the manufacturers' tests on each lot of vaccine prior to distribution), and continues to monitor the safety of the vaccines once they are approved for use and in distribution.

FDA and CDC scientists routinely evaluate reports to the Vaccine Adverse Event Reporting System (VAERS) of health problems that may be associated with a vaccine (*www.fda.gov/biologicsbloodvaccines/safetyavailability/reportaproblem/vaccineadverseevents/overview/default.htm*).

FDA conducts yearly surveillance for Guillain-Barre syndrome, a rare neurological condition associated with the 1976 flu vaccine, in collaboration with the Centers for Medicare and Medicaid Services. And the agency is now testing influenza surveillance in the new Mini-Sentinel Post Licensure Rapid Immunization Safety Monitoring (PRISM) system (*www.mini-sentinel.org*). If testing proves successful, FDA will be able to monitor rates of health problems after influenza vaccination among members of multiple health plans that serve the general U.S. population.

CDC also monitors the safety of annual influenza and other vaccines through the Vaccine Safety Datalink (VSD) (*www.cdc.gov/vaccinesafety/Activities/VSD.html*) by almost real-time observation of the health of people who are vaccinated, in collaboration with nine integrated health care organizations.

Who's Most Affected So Far?

CDC tracks influenza activity year round in the U.S. and typically children and seniors are most at risk for influenza, but occasionally a flu virus will circulate that disproportionately affects young and middle-aged adults. So far, data reported by CDC suggest that 2013-2014 could be such a flu season.

CDC received an unusually high number of reports of severe respiratory illness among young and middle-aged adults in the last two months of 2013. Many of the cases were associated with the H1N1 strain of influenza that affected children and young adults compared to older adults during the 2009 influenza pandemic. The 2009 H1N1 virus has circulated each year since the pandemic. It is not known if those most severely affected received a vaccine, but this particular strain is included in this year's vaccine and will help provide protection.

"Influenza seasons and severity are often unpredictable. Annual influenza vaccination is the best way to prevent influenza among people 6 months of age and older," says Gruber. "However, taking such practical measures as washing hands, covering coughs and sneezes and staying home when sick can also help to decrease the spread and minimize the effects of flu."

In addition, while antiviral drugs are not a substitute for vaccine, they can help to treat influenza. Tamiflu (oseltamivir phosphate) and Relenza (zanamivir) are the two FDA-approved influenza antiviral drugs recommended by CDC for use against recently circulating influenza viruses.

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